REMARKS

The Amendments

Claim 53 is amended for clarification purposes. As was clear from the election pursuant to the restriction requirement, the elected invention was the compounds wherein none of the bonds in formula I showing also a dotted line represented a double bond. The claims were amended with the intention of restricting them to this elected invention. But, as indicated in the Office Action, the amendment was not deemed to make this clear. The above amendment replaces the formula with a new formula wherein the dotted line are removed to make clear that all of these bonds are single bonds. Accordingly, the recitation about the meaning of the dotted lines is removed. Claims 68 and 78 are amended to make obvious clarifications.

The amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability. The amendments should not be interpreted as an acquiescence to any objection or rejection made in this application.

Restriction/Non-Elected Invention

As discussed above, it is believed to be quite clear now that the claims are directed only to the elected invention. The bonds in the B, C and D rings of formula I are all single bonds.

The Rejection under 35 U.S.C. § 112, First Paragraph

The rejection of claims 66-89 under 35 U.S.C. § 112, first paragraph, is respectfully traversed.

The claims, i.e., the method of treatment claims, are rejected for being non-enabled. The Office Action states that they are rejected because "they are too broad and the specification does not support how these diseases can be treated." The Office Action further points out that there is only one working example of a method according to the invention.

Initially, it is pointed out that it is improper to reject claims, under 35 U.S.C. § 112, first paragraph, or otherwise, for being "too broad." Further, as stated in M.P.E.P. § 2164.02:

> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

It is urged that practicing the instant invention, as claimed, does not require undue experimentation in view of the teachings provided by applicants' disclosure in view of what was known to one of ordinary skill in the art. The disclosure clearly enables practicing of at least one embodiment of the invention of each claim, and enablement of only one embodiment of the claim is necessary for the claim to be enabled.

It should be further noted that all the method claims depend on claim 66 and all the claimed methods fall under the general category of methods for treating an estrogen-deficiency-induced disease. Thus, the characterization of the "Nature of the Invention" in the Office Action as relating to 16 listed and "many more" different methods of treatment is not accurate. All the methods of treatment stem from the particularly discovered activity of the compounds, such as stated on page 1, first paragraph, of the specification. All of the methods are within the genus of methods for treating an estrogen-deficiency-induced disease.

Contrary to the allegation in the Office Action, the claimed methods do not relate to an unpredictable art. For example, methods for hormone replacement therapy using natural and synthetic steroids have been known and practiced for years. See, e.g., the entire

"Background of the Invention" discussion at pages 1-5 of the instant disclosure. The disclosure makes clear that the invention lies in the novelty and nonobviousness of the compounds and that such compounds are used in a manner analogously known for existing compounds used to treat estrogen-deficiency-induced diseases; see, e.g., page 39-43 of the specification. Thus, given applicants' disclosure of the claimed compounds, how to prepare them and a description of their activity, it would have been clear to one of ordinary skill in the art how to use all the claimed compounds in methods analogous to known methods for treating an estrogen-deficiency-induced disease. The Office Action gives no evidence or other basis for its allegation of the high unpredictability of the art.

Also contrary to the allegation in the Office Action, the teachings of how to use the invention in the specification are not "contrary to accepted scientific principles." There is no basis for such allegation whatsoever.

Additionally, it is urged that the PTO has not provided the requisite evidence or objective reasoning substantiating the allegation that the enabling disclosure is not commensurate in scope with the claims. In re Marzocchi et al., 169 USPQ 367 (CCPA 1971). As stated in Marzocchi:

> ".. a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein..",

and further,

> "..it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." (emphasis original).

No evidence or objective reasoning has been provided here which sheds any doubt on the truth or accuracy of applicants' statements in the specification that the entire scope of the claimed invention can be used in the manner stated, i.e., that the compounds have the stated activity and, therefore, can be used in methods where such activity was already known to have usefulness. See also M.P.E.P. § 2164.04, as to the burden of proof being on the PTO.

For all of the above reasons, it is urged that the instant claims are enabled to one of ordinary skill in the art and that the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

The Rejection under 35 U.S.C. § 102

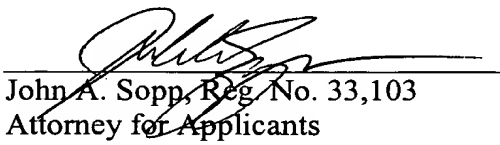
The rejection of claims 53 and 65 under 35 U.S.C. § 102(b) as being anticipated by Fishman (DN 53:17432 CAPLUS abstract) is respectfully traversed.

The compound shown in the Fishman abstract and reproduced in the Office Action is estra-1,3,5(10)-triene-3,16β-diol. This compound is excluded from the literal scope of the instant claims by the proviso in instant claim 53. See the second compound excluded in the proviso at the end of claim 53. Thus, the compound does not meet the elements of the any of the instant claims and the rejection under 35 U.S.C. § 102 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



John A. Sopp, Reg. No. 33,103
Attorney for Applicants

MILLEN, WHITE, ZELANO &
BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

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